IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:		§	Group Art Unit: 2829
	Sharan et al.	§	
		§	Examiner: Lisa Kilday
Serial No.:	09/825,613	§	
		§	Atty. Docket: 95-0716.03
Filed:	April 3, 2001	§	
For: METHOD FOR PECVD DEPOSITION OF SELECTED MATERIAL FILMS		§	

APPLICANTS' BRIEF ON APPEAL

Certificate of Mailing (37 C.F.R. § 1.8)

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APPLICANTS' BRIEF ON APPEAL

I. REAL PARTY IN INTEREST

The Applicants, Sujit Sharan and Gurtej S. Sandhu, have assigned their interest in this application to Micron Technology, Inc.

II. RELATED APPEALS AND INTERFERENCES

Applicants are concurrently filing an Appeal Brief in further prosecution of U.S. App. Ser. No. 09/825,612, which was filed 4/03/01 and is a sibling of the currently appealed application ('612 is a divisional and this application is a continuation of U.S. App. Ser. No. 09/249,478, filed 2/12/99 and issued as U.S. Pat. No. 6,291,341).

III. STATUS OF THE CLAIMS

Claims 1-66 have been presented during prosecution of the application under appeal.

Claims 5-28 and 30-66 have been canceled.

Claims 1-4 and 29 are pending.

Claims 1-4 and 29 are rejected.

Claims 1-4 and 29 are appealed.

IV. STATUS OF THE AMENDMENTS

Applicants filed no amendments subsequent to final rejection.

V. SUMMARY OF THE INVENTION

The current invention addresses a PECVD deposition process. (Specification at **[0023]**.) In one embodiment, that process comprises the acts of providing an ion promoting atmosphere (***id***. at **[0037]**-**[0038]**; *see also* Office Action dated 4/9/03 at p. 2); and contacting a substrate with

a plasma (Specification at **[0014]**, **[0029]**). That embodiment further requires that the plasma is approximately 50 to 90 % of a metal-containing gas. (***Id***. at **[0040]**.) That embodiment still further requires that contacting occur in the ion-promoting atmosphere. (***Id***. at **[0031]**, **[0042]**.) A more detailed embodiment of this type requires that the act of providing an ion promoting atmosphere comprises selecting the atmosphere from a group consisting of nitrogen gas, argon gas, neon gas, krypton gas, xenon gas, helium gas and radon gas. (***Id***. at **[0029]**, **[0037]**-**[0038]**.) In another more detailed embodiment of this type, the act of contacting a substrate with a plasma comprises having a temperature range of approximately 150 to 500 degrees Celsius. (***Id***. at **[0027]**.) In yet another more detailed embodiment of this type, the act of contacting a substrate with a plasma comprises having a pressure range of 1 mTorr to 10 Torr. (***Id***.)

In another more general embodiment, the PECVD deposition process comprises the acts of maintaining a pressure and a temperature which allow for PECVD metal-containing film deposition (***id***. at **[0027]**); and contacting a surface with a plasma of approximately 50 to 90% metal-containing compound (***id***. at **[0040]**) in a chemically inert atmosphere (***id***. at **[0029]**, **[0037]**-**[0038]**).

VI. ISSUES

There are four issues for determination on appeal.

1. Whether the Examiner's citation to enabling text in the Specification and admission refutes the 35 U.S.C. §112, ¶1 rejection based on the phrase "ion promoting atmosphere."

2. Whether the Specification enables "a plasma of approximately 50 to 90 % of a metal-containing gas," thereby refuting the 35 U.S.C. §112, ¶1 rejection based on that phrase.

3. Whether the Specification and plain language support definiteness of "a plasma of approximately 50 to 90 % of a metal-containing gas," thereby refuting the 35 U.S.C. §112, ¶2 rejection based on that phrase.

4. Whether the Examiner's citations to Zhao, relied upon for the 35 U.S.C. §102 rejection, fail to support the Examiner's interpretation of that reference.

VII. GROUPING

Applicants define the following groups of claims for consideration upon this appeal. The groups correspond to the issues listed above.

Group I: claim 1;

Group II: claim 1;

Group III: claim 1; and

Group IV: 1-4 and 29 (the claims do not necessarily fall together).

VIII. ARGUMENT

The Examiner rejected claim 1 under 35 U.S.C. §112, ¶1 as lacking enablement based on two phrases in the claim. The Examiner also rejected claim 1 under 35 U.S.C. §112, ¶2 as lacking definiteness based on one of those phrases. The Examiner further rejected claims 1-4 and 29 under 35 U.S.C. §102(e) in light of U.S. Pat. No. 6,051,286 by Zhao et al. Applicants contend that the statements found in the Specification and made by the Examiner support the enablement and definiteness of claim 1. Further, the statements made by the Examiner in attempting to anticipate claims 1-4 and 29 are not supported by the excerpts of Zhao cited by the Examiner. Applicants detail the traversal of each basis for rejection separately below.

A. The Examiner's citation to enabling text in the Specification and admissions refute the 35 U.S.C. §112, ¶1 rejection based on the phrase "ion promoting atmosphere"

Claim 1 requires an act of providing an ion promoting atmosphere as part of a process of PECVD deposition. The Examiner argued that the term "ion promoting atmosphere" is not enabled in the Specification. (Office Action dated 4/9/03 at p. 2.) In an attempt to support this argument, the Examiner curiously cited portions of the Specification, indicating that those

portions teach an ion promoting atmosphere that can contain inert/noble gases, combinations of inert/noble gases, and non-inert/reactive gases. (***Id.*** (citing paragraphs **[0037]** and **[0038]** of the Specification).) Applicants contend that the Examiner's citations and admission actually support enablement and refute this basis for rejection.

The Examiner made an additional admission that further supports enablement. This admission is relevant to the tenet that enablement is determined from the viewpoint of a person skilled in the field of the invention. (***Ajinomoto Co. v. Archer-Daniels-Midland Co.***, 228 F.3d 1338, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000). A copy of ***Ajinomoto*** is included in an appendix to this Appeal Brief.) Applicants note that the MPEP echoes this same tenet found in binding case precedent. Specifically, MPEP §2164.08 emphasizes all that is necessary for enablement is that one skilled in the art be able to practice the invention, given the level of knowledge and skill in the art. (A copy of MPEP §2164.08 is also included in an appendix to this Appeal Brief.)

Significant to this tenet is the fact that, after citing paragraphs in the Specification that enable an ion promoting atmosphere, the Examiner then admitted that

> [t]he selection of the ion promoting gas will greatly vary the material deposited and may result in a dielectric to be deposited. For example, if oxygen is chosen as the ion promoter gas, you will deposit Titanium (sic) oxide . . . .

(Office Action dated 4/9/03 at p. 2.) Applicants contend that the Examiner's (1) awareness that gas selection can affect a deposited film; and (2) ability to make such a selection demonstrates that the standard "person skilled in the field of the invention" would also have such awareness and ability. With such awareness and ability, Applicants contend that the artisan would find that the Specification (including the paragraphs cited by the Examiner) enables claim 1 in terms of its "ion promoting atmosphere."

Returning to the Examiner's hypothetical embodiment quoted above, the Examiner concluded that such an embodiment results in depositing a dielectric, not a metal. (Office Action dated 4/9/03 at p. 2.) The Examiner further announced that it is impossible to determine from claim 1 a suitable ion promoter gas that will deposit a metal. (***Id.***) Applicants note that claim 1 is not limited to depositing a dielectric or metal. Although claim 1's preamble once referred to deposition of metal films, it no longer does. Hence the Examiner's focus on depositing a

dielectric or metal is no longer applicable. The Examiner later argues that such breadth in claim scope doesn't cure claim 1's enablement issue. (Office Action dated 4/9/03 at p. 5.) Applicants reiterate that Examiner's own citations to the Specification and admitted ability to appreciate and apply factors relevant to deposition demonstrate that the Specification provides commensurate enablement for skilled artisans. (*See* MPEP 2164.08.)

B. The Specification enables "a plasma of approximately 50 to 90 % of a metal-containing gas," thereby refuting the 35 U.S.C. §112, ¶1 rejection based on that phrase.

Claim 1 also requires an act of contacting a substrate with a plasma of approximately 50 to 90 % of a metal-containing gas. The Examiner argued that such a plasma is not enabled by the Specification. (Office Action dated 4/9/03 at p. 2-3.) Actually, the Examiner went even further, arguing that the Specification cannot enable such a plasma based on the flow rates disclosed in paragraph **[0027]**. (***Id***. at p. 3.) Without specifically addressing whether these flow rates enable claim 1's plasma, Applicants alert the Board that the disclosure in paragraph **[0027]** provides non-limiting enablement for at least one embodiment within the scope of the invention. Other paragraphs provide non-limiting enablement for other embodiments within the scope of the invention. One such paragraph particularly relevant to claim 1's plasma is paragraph **[0040]** of the Specification:

> Concerning the plasma, the parameters used in carrying out some embodiments will result in an inductively coupled, high density *plasma* (IC HDP) *containing approximately 50 to 90% of a metal-containing gas*. Process pressures for such an IC HDP reactor 10 may be in the range of 1 mTorr to 10 Torr and with combined gas flow rates in the range of 100 to 800 sccm. In addition, some embodiments result in a high density plasma – containing approximately 10^{11} to 10^{13} ions/cm^3.

(***Id***. (emphasis added).)

Applicants have cited this paragraph to the Examiner before in support of enablement. (*See* Second Amendment and Response to the Office Action of 9/12/02 at p. 2.) The Examiner remains unpersuaded for three reasons. (Office Action dated 4/09/03 at p. 5.) First, the Examiner noted that Applicants did not previously address paragraph **[0027]**. Applicants have addressed it

above, indicating that it provides non-limiting enablement for at least one embodiment within the scope of the invention. Second, the Examiner perceived a conflict between paragraphs **[0027]** and **[0040]**. Applicants reiterate that there is no conflict: at worst, the two paragraphs enable two different embodiments within the scope of the invention. Third, the Examiner complains that paragraph **[0040]** does not state the metal composition of the plasma. Applicants reemphasize that paragraph **[0040]** expressly states a "plasma . . . containing approximately 50 to 90% of a metal-containing gas."

Thus, because the Specification (1) expresses the same language as the relevant claim phrase; and (2) is in harmony with the rest of the Specification, Applicants contend that a plasma of approximately 50 to 90 % of a metal-containing gas is enabled.

C. The Specification and plain language support definiteness of "a plasma of approximately 50 to 90 % of a metal-containing gas," thereby refuting the 35 U.S.C. §112, ¶2 rejection based on that phrase.

The Examiner also rejected claim 1 under §112 ¶2 as being indefinite in light of the "approximately 50 to 90 % of a metal-containing gas" language discussed above. (Office Action dated at 4/09/03 at p. 3-4.) The Examiner attempted to propose two alternative definitions to demonstrate the indefiniteness of the phrase. (***Id.***) Applicants can discern no substantive difference between the Examiner's two definitions and urge the Board to adopt the plain meaning of the limitation: claim 1 requires an act of contacting a substrate with a plasma; the plasma is approximately 50 to 90 % of a metal-containing gas; and contacting occurs in an ion-promoting atmosphere. Such an interpretation has the added benefit of being consistent with paragraph **[0040]** of the Specification.

The Examiner adds that the Specification cannot satisfy the definiteness requirement given the flow rates disclosed in paragraph **[0027]**. Applicants contend that the supporting paragraph discussed above -- paragraph **[0040]** -- provides sufficient definiteness and refutes the Examiner's proposition that definiteness cannot be provided.

D. The Examiner's citations to Zhao, relied upon for the 35 U.S.C. §102 rejection, fail to support the Examiner's interpretation of that reference.

The Examiner rejected claims 1-4 and 29 as being anticipated by U.S. Pat. No. 6,051,286 by Zhao et al. Applicants contend that the portions of Zhao cited by the Examiner do not support the Examiner's conclusions and do not disclose all of the claim limitations. For example, in attempting to reject claim 1, the Examiner cites Zhao's column 36, lines 21-24 and 41-67. However, those excerpts merely disclose gas delivery. Specifically, Zhao's lines 21-24 merely disclose turning on a reactant gas such as hydrogen at an initial flow rate, wherein the reactant gas lowers the energy required for decomposing a source gas to form a desired film. Zhao's lines 41-67 merely further address gas delivery, detailing factors such as turning on a source gas; a reactant/source gas flow ratio; a specific source gas – He; bubbling He through liquid $TiCl_4$ at 60°C; the pressure above that liquid; the flow rate of He; a combined He and $TiCl_4$ flow; the effect of a mass flow controller on the gas flows; the results of heating $TiCl_4$; choosing pressures of various gases for high film deposition rate; and a throttle valve. Applicants submit that the Board will find nothing about claim 1's requirement of contacting a substrate with a plasma of approximately 50 to 90 % of a metal-containing gas. Hence, the Examiner has failed to satisfy the burden for rejecting claim 1. Dependent claims 2-4 benefit accordingly.

Moreover, the Examiner's attempt to cite a portion of Zhao against a limitation in at least one of the dependent claims suffers a similar problem. Specifically, in attempting to reject claim 2, the Examiner cites column 2, lines 10-12 of Zhao for the proposition that Zhao teaches helium as an ion promoting gas. (Office Action dated at 4/09/03 at p. 4.) Applicants submit that the Board will find nothing about helium or ion promotion in that excerpt. As a result, the Examiner has further failed to satisfy the burden for rejecting claim 2. Applicants note that this additional failure is particular to claim 2 and may warrant claim 2's allowance even if the Board supports the claim 1 rejection. Hence, the claims do not necessarily fall together.

In attempting to reject claim 29, the Examiner once again cites Zhao's column 36, lines 21-24 and 41-67. Applicants have already discussed the disclosure of those excerpts above. Just as those excerpts fail to disclose claim 1's requirement of contacting a substrate with a plasma of approximately 50 to 90 % of a metal-containing gas, so too do those excerpts fail to disclose claim 29's requirement of contacting a *surface* with a plasma of approximately 50 to 90 % metal-

containing *compound*. Hence, the Examiner has failed to satisfy the burden for rejecting claim 29.

E. Conclusion

The Examiner's own citations to the Specification demonstrate enablement commensurate with scope established by claim 1's requirement of providing an ion promoting atmosphere. Enablement concerning this limitation is further supported by the Examiner's admitted understanding that deposition is determined by gas selection (and the Examiner's ability to make such a selection), which suggests that a skilled artisan would have a similar understanding (and ability).

Applicants' citation to paragraph **[0040]** of the Specification demonstrates enablement of claim 1's requirement for a plasma of approximately 50 to 90 % of a metal-containing gas. To the extent the Board adopts the Examiner's argument that paragraph **[0027]** is contradictory, Applicants request that the Board interpret the two paragraphs as enabling alternative embodiments within the scope of the invention. Such an interpretation would have the benefit of giving meaning to both portions of the Specification. Applicants' citation to paragraph **[0040]** of the Specification also demonstrates the definiteness of claim 1's requirement for a plasma of approximately 50 to 90 % of a metal-containing gas, as does the plain meaning of the phrase.

Finally, the Examiner's citations to Zhao do not support the Examiner's conclusions concerning Zhao's disclosure, as a careful reading demonstrates. As a result, the Examiner has failed to satisfy the burden for rejecting the appealed claims as being anticipated by Zhao.

Accordingly, Applicants request that the Board reverse the Examiner, withdraw the rejections, and allow claims 1-4 and 29.

Respectfully submitted,

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Appendix 1: Copy of Involved Claims

1. A process of PECVD deposition comprising the steps of:

providing an ion promoting atmosphere; and

contacting a substrate with a plasma of approximately 50 to 90 % of a metal-containing gas in said ion promoting atmosphere.

2. The process of claim 1 wherein said step of providing an ion promoting atmosphere comprises selecting said ion atmosphere from a group consisting of nitrogen gas, argon gas, neon gas, krypton gas, xenon gas, helium gas and radon gas.

3. The process of claim 1 wherein said step of contacting a substrate with a plasma comprises having a temperature range of approximately 150 to 500 degrees Celsius.

4. The process of claim 1 wherein said step of contacting a substrate with a plasma comprises having a pressure range of 1 mTorr to 10 Torr.

29. A process for PECVD deposition of metal-containing films on a surface, the process comprising:

maintaining a pressure and a temperature which allow for PECVD metal-containing film deposition; and

contacting said surface with a plasma of approximately 50 to 90% metal-containing compound in a chemically inert atmosphere.

Appendix 2:

Ajinomoto Co. v. Archer-Daniels-Midland Co., 228 F.3d 1338, 56 U.S.P.Q.2d 1332 (Fed. Cir. 2000).

Briefs and Other Related Documents

Ajinomoto Co.
v.
Archer-Daniels-Midland Co.

U.S. Court of Appeals Federal Circuit

Nos. 99-1098, -1099, -1209, -1210

Decided October 3, 2000

PATENTS
[1] Title -- Assignments (§ 150.03)

JUDICIAL PRACTICE AND PROCEDURE
Procedure -- Parties; standing (§ 410.07)

Federal district court properly concluded that plaintiff established its standing to sue for patent infringement, since complaint contained approximate statement of plaintiff's standing, and record identified exclusive invention licensing agreement assigned by technology licensing agency of former Soviet Union to genetic engineering institute, assignment of patent from institute to plaintiff, and assignment of patent by inventors directly to plaintiff, and since defendant presented no evidence to impugn prima facie effectiveness of these documents to transfer patent rights.

PATENTS
[2] Practice and procedure in Patent and Trademark Office -- Prosecution -- Applicants for patent (§ 110.0917)
Infringement -- Defenses -- Fraud or unclean hands (§ 120.1111)

Federal district court did not err in holding that invalidity of patent based on irregularities in signing procedures required showing, by clear and convincing evidence, of fraud or inequitable conduct by inventors, since law does not bar correction of defect in patent application if defect was not product of fraud; defendant failed to present evidence sufficient to establish material misrepresentation and deceptive intent on part of inventors of patent in suit, some of whom authorized others to sign U.S. application for them, but subsequently filed declaration stating that signing irregularities resulted from their lack of knowledge of U.S. patent law.
[3] Patentability/Validity -- Specification -- Enablement (§ 115.1105)

Patent for method of modifying genetic structure of bacteria to produce increased quantities of amino acids is not invalid for lack of enablement, since process used conventional and well-known genetic engineering techniques, and since applicant's deposit of four bacterial strains specifically described in patent, in accordance with 35 U.S.C. § 122, satisfies enablement requirement for materials that are not amenable to written description, or that constitute unique biological materials which cannot be duplicated.
[4] Patentability/Validity -- Specification -- Best mode (§ 115.1107)

Relevant scientific knowledge set forth in prior art references need not be included in patent document, since requiring inclusion in patent of known scientific or technological information would add imprecise and open-ended criterion to content of patent specifications, could greatly enlarge content of patent specifications and unnecessarily increase cost of preparing and prosecuting applications, and could tend to obfuscate rather than highlight contribution to which patent is directed.
[5] Infringement -- In general (§ 120.01)

Unauthorized importation of product made abroad by process covered by U.S. patent infringes that patent under 35 U.S.C. § 271(g), even if product was made abroad with authority of patentee, since Section 271(g) applies to unauthorized actions within United States, and it is irrelevant that product was authorized to be produced outside United States; if process used abroad is covered by U.S. patent, then liability for infringement arises only upon importation, sale or offer of sale, or use in United States as set forth in Section 271(g).

REMEDIES
[6] Monetary -- Damages -- Patents -- In general (§ 510.0507.01)

Federal district court did not abuse its discretion by denying patent infringement defendant's motion to amend judgment against it on ground that it had discontinued use of infringing strain of bacteria on final day of testimony at trial, since only defendant was privy to knowledge that it had changed to assertedly non-infringing bacterial culture, but it did not provide information about change until after entry of judgment, and provided explicit testimony at trial that it was using infringing strain, and since defendant offered no explanation for its silence on this matter; however, court erred in including, in measure of damages, product produced during period between entry of final judgment and defendant's filing of motion to amend, since motion reasonably placed at issue its continued

infringement after judgment.

PATENTS
Particular patents -- Chemical -- Amino acid production
4,278,765, Debabov, Kozlov, Zhdanova, Khurges, Yankovsky, Rozinov, Shakulov, Rebentish, Livshits, Gusyatiner, Mashko, Moshentseva, Kozyreva, and Arsatiants, method for preparing bacterial strains which produce amino acids, judgment holding patent infringed, not invalid, and enforceable affirmed.

***1333** Appeal from the U.S. District Court for the District of Delaware, Robinson, J.

Action by Ajinomoto Co., Inc. against Archer-Daniels-Midland Co. for patent infringement. Defendant appeals from judgment holding plaintiff's patent infringed, not invalid and enforceable, and plaintiff appeals from ruling that infringement was not willful. Affirmed; damages modified.

Marc R. Labgold and Catherine B. Richardson, of Piper, Marbury, Rudnick & Wolfe, Washington, D.C.; Arthur I. Neustadt, of Oblon, Spivak, McClelland, Maier & Neustadt, Arlington, Va., for plaintiff.

Charles A. Laff, Kevin C. Trock, Martin L. Stern, William A. Meunier, and Lisa C. Childs, of Laff, Whitesel, Conte & Saret, Chicago, Ill.; Ari S. Zymelman, of Williams & Connolly, Washington; Jack B. Blumenfeld, of Morris, Nichols, Arsht & Tunnell, Wilmington, Del., for defendant.

Before Newman, circuit judge, Smith, senior circuit judge, and Rader, circuit judge.

Newman, J.

Archer - Daniels - Midland Company ("ADM") appeals the judgment of the United States District Court for the District of Delaware, [FN 1] holding that ADM's use of certain strains of genetically modified bacteria to produce the amino acid threonine infringed Ajinomoto's United States Patent No. 4,278,765 ("the '765 patent") in terms of 35 U.S.C. § 271(g), and awarding damages calculated as a royalty of $1.23/kg of threonine produced by ADM from May 1993 to March 27, 1998. ADM also appeals the district court's ruling that the '765 patent is valid and enforceable. Ajinomoto cross-appeals the ruling that infringement was not willful. The judgment is affirmed, with modification of the damages period.

BACKGROUND

Threonine is an essential nutrient amino acid for many animals. It is not produced in the mammalian body and must be obtained from food. Bacteria, however, normally produce the amino acids needed for their own nutrition. The bacterial process, as it occurs in nature, is internally regulated to limit amino ***1334** acid production to the amount and kind required by the bacteria for their metabolic functions, and the amino acids produced are degraded as they are metabolized. The '765 patent, entitled "Method for Preparing Bacterial Strains Which Produce Amino Acids," is directed to modification of the bacterial genetic structure in order to produce amino acids in increased quantities. The patented method is based on a combination of mutation genetics and recombinant DNA technology. [FN 2]

The invention that is the subject of the '765 patent is the work of scientists at the Institute for Genetic Engineering and Industrial Microbiology ("Genetika") in the former Soviet Union. The patent describes and claims the modification of bacteria in order to block both the regulatory mechanism that limits amino acid production and the degradation pathway for the amino acid that is produced, leading to bacterial overproduction of the amino acid. That is, each bacterium produces more of the amino acid than it needs, and does not metabolize the excess amino acid that it produces. When conducted on a suitably large scale, commercial quantities of amino acid are obtained. Threonine is included in balanced animal feed supplements, and is of commercial value.

The '765 patent describes a strain of *E. coli* bacteria that normally produces and consumes threonine. This strain was mutated to a strain that was "feedback resistant" to the production of threonine; that is, a strain that did not limit the amount of threonine produced to what was needed for the bacterial metabolism. From this mutant strain the portion of the chromosome containing the mutated gene controlling the synthesis of threonine was isolated. This chromosome fragment (called a threonine "operon") was then combined with a plasmid [FN3] that had been found to be suitable for inserting this genetic material into a host bacterium, to produce a "hybrid plasmid." The hybrid plasmid was then inserted into a "recipient" changed or mutated host bacterial strain that was modified to have two characteristics: it was incapable of producing the desired amino acid before insertion of the hybrid plasmid, and it contained a mutation that partly blocked its natural mechanisms for degrading

the desired amino acid. The new bacterial strain thus formed, when placed in an appropriate medium, produces an excess of the desired amino acid. According to the record, this had never before been accomplished.

An application for an Inventors' Certificate was filed in the Soviet Union on June 30, 1978. A corresponding United States patent application was filed on June 28, 1979 and issued as the '765 patent on July 14, 1981. Ajinomoto is the owner of the '765 patent, having acquired Genetika's United States patent rights. Claims 1 and 2 of the '765 patent are in suit:

1. A method for preparing bacterial strains which produce aminoacids comprising

combining a chromosome DNA fragment of a donor bacterium containing genes controlling the synthesis of a selected aminoacid and having a mutation which destroys the negative regulation of the synthesis of said aminoacid, with a plasmid DNA molecule capable of ensuring amplification, to form a hybrid DNA molecule;

transforming with said hybrid DNA molecule, cells of a recipient bacterial strain having a mutation blocking the synthesis of the selected aminoacid in said strain and a mutation partly blocking the related step of metabolism of said aminoacid,

to yield a bacterial strain possessing increased productivity of the selected aminoacid.

2. A method as claimed in claim 1, wherein for the removal of ballast genetic material, the hybrid DNA molecule is treated, prior to transforming cells of the recipient strain, with specific endonucleases ensuring cleavage of the hybrid molecule of DNA in predetermined sites of the molecule, followed by recombination and joining of the required DNA fragments with polynucleotide ligase.

In 1993 ADM, a producer of feed supplements for livestock, commenced the production of threonine using a bacterial strain that was made in Sweden by ABP International, a ***1335** Genetika licensee using the Genetika process. ABP's license was territorial, and granted no rights in the United States. ADM purchased the bacterial strains and strain documentation and the right to use the bacteria for the production of threonine of feed grade quality, along with the specifications and operating manual for the design and construction of a plant to produce threonine using the designated process.

Ajinomoto sued ADM, invoking 35 U.S.C. § 271(g) and charging that the genetically engineered bacteria imported by ADM and used in the United States infringed the '765 patent because the bacteria were made by the method patented in the United States.

STANDING TO SUE

After trial was over, ADM challenged Ajinomoto's standing to sue for infringement of the '765 patent. ADM challenged the license to Ajinomoto from the Soviet licensing agency and the subsequent direct assignment by the inventors to Ajinomoto. The district court, despite finding that ADM had raised the issue tardily, considered the question in light of the information of record.

The district court determined that the Soviet government owned the Genetika invention and that Licensintorg, the Soviet government's technology licensing agency, had the right to grant a license to Ajinomoto. The court explained that "even though the Inventors' Certificate was issued in the names of the inventors, according to Soviet law, the invention became the property of the Soviet government." In 1991 the Russian state returned patent ownership and any license agreements to the various entities from which they originated. In May 1991 Genetika assigned the '765 patent to Ajinomoto, and in October 1991 the inventors executed an assignment directly to Ajinomoto. The district court found the evidence in the record sufficient to establish Ajinomoto's ownership of the '765 patent and its standing to sue for infringement.

[1] We agree that the 1982 exclusive license from Licensintorg, in which no substantial right was retained by the Soviet government or any other entity, as well as the ensuing assignments of the ownership rights of Genetika and of the inventors, conveyed all substantial rights to the '765 patent. ADM argues that "the record contains no written transfer of title to the '765 patent from the inventors," apparently referring to transfer from the inventors to the Soviet state for the purposes of Licensintorg's grant of an exclusive license to Ajinomoto in 1982. However, it is not disputed that the inventors were all employed at Genetika, a Soviet institution, and that they made the invention in the course of their employment. ADM argues that there is no evidence of record of Soviet law concerning the transfer of patent rights by employed inventors, including rights to foreign patents. However, ADM proffered no

evidence and offered no argument of any flaw or illegality under Soviet law.

The district court observed that although "neither Ajinomoto nor the court was sufficiently put on notice that standing was a contested issue," standing was established by the evidence of record. ADM presented and presents no evidence to negate the unchallenged Licensintorg representations and grant of rights in the exclusive license agreement. It is well established that the holder of all substantial patent rights, by assignment or by exclusive license, has standing to sue for infringement in its own name. *See, e.g., Vaupel Textilmaschinen KG V. Meccanica Euro Italia S.P.A.*, 944 F.2d 870, 875, 20 USPQ2d 1045, 1049 (Fed. Cir. 1991).

With respect to the assignment by the inventors, ADM argues that the recorded assignment was not entered into evidence, although it was identified on an exhibit list. The district court observed that ADM's delay in raising the standing issue until after trial "effectively prevented Ajinomoto from offering into evidence the pertinent provisions of Soviet law or the purported assignment to Ajinomoto by the inventors that is recorded in the PTO." We agree that ADM is now estopped to object that the recorded assignment was not entered into evidence; further, it is a public record of the United States Patent and Trademark Office, and its existence is not disputed.

A challenge to "standing," after standing has been *prima facie* established, requires some degree of plausibility. Ajinomoto's complaint contained an appropriate statement of its standing, and the record before the district court identified the exclusive license agreement from Licensintorg, the assignment of this agreement to Genetika, the assignment of the patent from Genetika to Ajinomoto, and the assignment of the patent by the inventors to Ajinomoto. ADM presented no evidence to ***1336** impugn the *prima facie* effectiveness of these documents to transfer patent rights.

The district court concluded correctly that Ajinomoto's standing to sue for infringement of the '765 patent had been established. This ruling is affirmed.

VALIDITY

Signatures of the Inventors

ADM argues that the United States patent application was improperly executed, that the flaws are irremediable, and that this invalidates the '765 patent.

The Russian application for Inventors' Certificate named fourteen inventors. ADM does not challenge that this application was personally signed by each of the fourteen inventors. One of the inventors, Dr. Kozlov, stated in his deposition testimony that he had not personally signed the corresponding United States application, but that his name had been signed in his absence with his authorization. ADM argued that this invalidated the United States patent, and could not be remedied by subsequent ratification. In addition, in 1980 Genetika filed a declaration in the PTO stating that strains of the bacteria had been deposited in Genetika's culture depository and that the deposits would be available to the public; ADM charges that not all fourteen inventors personally signed this declaration, and that this too invalidated the patent and could not be remedied.

These issues were raised during the litigation, and on August 5, 1996 Ajinomoto filed a declaration with the PTO, the Russian language version of which was signed by the fourteen inventors, stating that the filings wherein the signatures of some inventors were entered by others with the inventors' authorization "was the result of a lack of knowledge of the technical requirements of U.S. patent law and was made without any deceptive intent." ADM's handwriting expert compared the fourteen signatures on the 1996 declaration with the fourteen signatures on the declaration filed in 1980 and gave the opinion that six or possibly seven of the signatures were not written by the same person. ADM's expert conceded that the signatures were difficult to compare since those on the 1996 Russian document were written in the Russian (cyrillic) script, whereas those on the 1980 English document were written in English script. ADM complains that it was able to depose only Dr. Kozlov and Dr. Debabov, and states that Ajinomoto should have provided objective authentication of all of the signatures and should have produced the fourteen inventors at the trial.

The district court, receiving the evidence and hearing the argument, ruled that invalidity based on the signing procedures required a showing of clear and convincing evidence of fraud or inequitable conduct by the inventors. ADM argues that the Russian inventors had deceptive intent when they filed the United States patent application and the 1980 declaration. The district court found that there was not evidence to support this position. The court ruled that technical

errors, made without deceptive intent, could not be the basis for holding the patent invalid or unenforceable, citing *In re Bennett*, 766 F.2d 524, 526-28, 226 USPQ 413, 415 (Fed. Cir. 1985) ("It is not in the public interest to bar all possibility of legal or equitable relief, when such is sought to correct a harmless error. Thus we consider the reality of the practice at issue, guided by legislative and judicial precedent, and mindful of the interest of justice.")

On appeal, ADM argues that the district court erred in requiring evidence of fraud or deceptive intent, and that the irregularities of signature rendered the patent invalid as a matter of law, and were incurable by any subsequent ratification. ADM cites *Kennedy v. Hazelton*, 128 U.S. 667 (1888) and similar cases for the argument that the inventor must personally sign the oath or the patent is invalid. The cited authority is inapt. In *Kennedy v. Hazelton* the inventor had attempted to evade a contractual obligation to assign improvements by causing a third person to apply for the patent in the third person's name. The Court held the patent invalid because it was applied for by a person who did not make the invention: "A patent which is not supported by the oath of the inventor, but applied for by one who is not the inventor, is unauthorized by law and void . . .." *Id.* at 672.

[2] The district court distinguished such fraudulent filings from a filing in which the inventors authorized others to sign the documents in ignorance of United States requirements, and for which remedial action was taken by the inventors. The law does not bar the correction of defects when the defect was not the product of fraud. The district court did ***1337** not err in requiring proof of fraud or inequitable conduct in order to preclude corrective action.

ADM also argues that the district court misplaced the burden of proof, that the burden was on Ajinomoto to prove the absence of deceptive intent in the signatures on the filings in 1979 and 1980, and that the 1996 declaration of the Russian inventors did not meet this burden with respect to events so many years earlier. However, the burden of proving that a patent is invalid is upon the party who asserts the defense. ADM also argues that it met the burden of proving deceptive intent, if it bore that burden, because Ajinomoto's explanation of the defective signatures was inadequate.

The district court found that ADM did not present evidence sufficient to establish the facts of material misrepresentation and deceptive intent, predicate to its assertion of fraud or inequitable conduct. *See Kingsdown Medical Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 872, 9 USPQ2d 1384, 1389 (Fed. Cir. 1988) (*en banc*) ("Inequitable conduct resides in failure to disclose material information, or submission of false material information, with an intent to deceive, and those two elements, materiality and intent, must be proven by clear and convincing evidence."); *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1417 n.11, 5 USPQ 1112, 1117 n.11 (Fed. Cir. 1987) (confirming that "a determination of 'inequitable conduct' may not be based on inferences").

Clear error has not been shown in the district court's findings on this issue. The court's ruling is affirmed.

Enablement

ADM argues that claims 1 and 2 of the '765 patent are not enabled as required by 35 U.S.C. § 112. ADM states that the '765 patent does not adequately teach how to identify the specific amino acid genes in the donor bacterium, how to obtain a chromosome DNA fragment, how to obtain suitable plasmids, how to isolate recipient bacterial strains, and how to perform the transformation step.

Enablement is determined from the viewpoint of persons of skill in the field of the invention at the time the patent application was filed. Experts for both sides testified as to all of the challenged aspects and as to the level of skill at the time. The district court, summarizing the evidence, found that the specification of the '765 patent enabled the scope of the claims. Responding to ADM's argument that the claims could cover myriad bacterial strains not yet known, the court stated:

According to the record, all of the methods needed to practice the invention were well known to those skilled in the art. Despite the diversity existing among bacteria, practitioners of this art were prepared to carry out the identification, isolation, recombination, and transformation steps required to practice the full scope of the claims.

Ajinomoto, 1998 WL 151411 at *44. *See Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986) ("a patent need not teach, and preferably omits, what is well known in the art.") On appeal ADM reargues this issue.

[3] The district court heard extensive testimony from qualified experts, with exploration of the technology

in light of the knowledge and publications at the time the patent application was filed. The court also pointed to the extensive exploration of enablement during examination in the PTO, when Ajinomoto had challenged this aspect of Genetika's patent before acquiring it:

Prior to becoming the assignee of the '765 patent, Ajinomoto argued, during the prosecution of seven patent applications, that the specification of the '765 patent did not enable the full scope of the claims. However, in each instance, the PTO Examiner rejected Ajinomoto's argument, finding that the patent was enabled since the types of mutations suggested by the patent were conventional and one skilled in the art could easily produce such mutants because genetic engineering techniques were conventional and well-known.

Ajinomoto, 1998 WL 151411 at 14-15 (Finding of Fact 57). The district court found, as had the examiner, that the process used conventional and well-known genetic engineering techniques. ADM has not shown clear error in the district court's findings and in the conclusion that invalidity on the ground of enablement has not been shown.

The district court also found that the enablement requirement had been met by deposit of the bacterial products in accordance with 35 U.S.C. § 122. The deposit of biological organisms for public availability satisfies the enablement requirement for materials that ***1338** are not amenable to written description or that constitute unique biological materials which can not be duplicated. As discussed in *In re Lundak*, 773 F.2d 1216, 1220-21, 227 USPQ 90, 93-94 (Fed. Cir. 1985), "When an invention relates to a new biological material, the material may not be reproducible even when detailed procedures and a complete taxonomic description are included in the specification." It is then a condition of the patent grant that physical samples of such materials be deposited and made available to the public, under procedures established by the PTO and by international treaty. *Id.*

The applicant deposited the four strains specifically described in the '765 patent for producing threonine: the donor strain MG442, the recipient strain VL334, and the products of claims 3 and 4, VL334 (pYN6) and VL334 (pYN7). ADM argues that the deposit did not establish enablement because requests for samples of the deposited microorganisms, by Degussa, a German company, and Eurolysine, a French firm, both of which manufacture threonine, were unsuccessful. The district court found that these requests had been properly denied because they did not comply with the procedures established in the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure. ADM does not dispute this finding, and offers no reason why the requests should have been granted if contrary to the treaty procedures. Error has not been shown in the district court's conclusion that the patent was not invalid on this ground.

Best Mode

ADM also argues that the '765 patent is invalid under 35 U.S.C. § 112 for failure to disclose the best mode of making and using the invention. In particular, ADM argues that the inventors did not explicitly state that the recipient bacterial strain was required to contain the relAk gene in order to achieve increased threonine production. ADM states that the most relevant scientific literature included two articles published by the inventors in *Genetika*, a Russian scientific publication, four months before their application for the Soviet Inventors' Certificate. ADM argues that the information in these articles should have been included in the patent application if it were to be relied upon for compliance with the best mode requirement.

ADM does not dispute the public availability of the *Genetika* publications, and that they are prior art to the '765 patent. The district court heard extensive expert testimony by both sides on the issue of the relAk gene and the disclosure of the best mode:

According to Dr. Rudolph [ADM's expert], one of ordinary skill in the art being familiar with the literature, particularly the Debabov article and Genetika I and II, would have been able to determine the best mode of practicing the '765 invention. Dr. Falkinham [Ajinomoto's expert] goes one step further concluding that one of ordinary skill in the art would have known that relAk is required to practice the claimed invention.

Ajinomoto, 1998 WL 151411 at *20 (Finding of Fact 77). ADM does not charge that this finding is in error, but argues that the relevant scientific knowledge should have been included in the patent document.

[4] The law has long recognized that such a requirement is unnecessary and inappropriate. *See In re Storrs*, 245 F.2d 474, 478, 114 USPQ 293, 296-97 (CCPA 1957) ("[I]t cannot be forgotten that the disclosure is not addressed to the public generally,

but to those skilled in the art.") Requiring inclusion in the patent of known scientific/technological information would add an imprecise and open-ended criterion to the content of patent specifications, could greatly enlarge the content of patent specifications and unnecessarily increase the cost of preparing and prosecuting patent applications, and could tend to obfuscate rather than highlight the contribution to which the patent is directed. A patent is not a scientific treatise, but a document that presumes a readership skilled in the field of the invention. *See W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1556, 220 USPQ 303, 315 (Fed. Cir. 1983) ("Patents, however, are written to enable those skilled in the art to practice the invention, not the public.")

Upon extensive analysis of the evidence, the district court found that the specification described the only and therefore the best mode known at the time the patent application was filed, and would be so recognized by persons skilled in the art:

The only mode for practicing the invention disclosed in the '765 patent is the description in the specification of the preparation ***1339** of strains VL334 (pYN6) and VL334 (pYN7). These strains were the only reductions to practice contemplated by the inventors at the time of the filing of the application. Although the specification does not expressly characterize the recipient strain VL334 as being relAk, it is undisputed that the parent strain of VL334, MG422, is relAk; thus, absent any indication of change to the relA gene, one skilled in the art would know that VL334 was also relAk.

Ajinomoto, 1998 WL 151411 at *42 (Finding of Law 36). No challenge is raised by ADM to the scientific premises and conclusions reached by the district court. The court's ruling based thereon, that the '765 patent has not been shown to be invalid on best mode grounds, is affirmed.

INFRINGEMENT

35 U.S.C. § 271(g) imposes liability for infringement by importation, sale, or use in the United States of a product made abroad by a process patented in the United States:

§ 271(g) Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. . . . A product which is made by a patented process will, for purposes of this title, not be considered to be so made after --(1) it is materially changed by subsequent processes; or (2) it becomes a trivial and nonessential component of another product.

Section 271(g) was enacted in 1988. Previously, the holder of a United States process patent had no recourse against one who practiced the process abroad and imported the product. The purpose of § 271(g) was to close this loophole and bring United States law into conformity with that of other nations. Thus § 271(g) imposes liability for infringement of the United States patent, with certain safeguards as set forth in the statute.

ADM's principal defenses were that the importation and use were authorized, and that the imported bacteria did not infringe correctly construed claims. Ajinomoto bore the burden of establishing that the imported strains were manufactured by a process covered by the '765 patent, and ADM bore the burden of establishing its defense that it had "authority" to perform the challenged actions. The district court found that bacterial strains G472T23 (pYN8), G472T23 (pYNSTOP), and G472T23 (pYNTE2) were made by the process claimed in the '765 patent, and that their importation and use infringed claims 1 and 2 of the '765 patent.

Importation "Without Authority" Under § 271(g)

ADM argues that "without authority" in § 271(g) means whether the patented process was authorized for practice abroad, and that § 271(g) does not prohibit importation into the United States of goods produced abroad with authority. ADM argues that practice of the accused process abroad and importation of the product into the United States were authorized because the Soviet agency Licensintorg in 1986 granted a license to the Genetika technology and the bacterial strain G472T23 (pYN7) to A.C. Biotechnics, a Swedish company that is predecessor to ABP International, the producer of the bacteria sold to ADM.

The license to A.C. Biotechnics granted "the exclusive right to use the licensed strain, knowledge and patents for the purpose of manufacturing of L-threonine in the territory [Belgium, Denmark, Finland, FRG, Holland, Iceland, Luxemburg, Norway, and Sweden] and the non-exclusive right to use and sell L-threonine, thus produced, in the territory and the zone of non-exclusive right [worldwide except the U.S.A.

and Japan]." ADM argues that this license of the Genetika invention would be meaningless if it did not confer the right to import the bacterial strains into the United States. ADM points out that a United States patent does not prohibit the practice abroad of an invention patented in the United States.

Ajinomoto responds that § 271(g) is not concerned with ABP's practice abroad, but applies only when there is imported into the United States a product that would infringe the United States patent if it were made in the United States. *See Biotechnology Gen'l Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1560, 38 USPQ2d 1321, 1326 (Fed. Cir. 1996). Ajinomoto points out that the license from Genetika explicitly excluded the United States, further negating ADM's argument of "authority." The district court held it irrelevant that Genetika, upon learning of ABP's violation of these territorial ***1340** limitations, did not act against ABP; we agree that Genetika's inaction did not enlarge ABP's license or diminish that of Ajinomoto. The district court correctly held that ABP's license did not provide authority to use and sell in the United States.

[5] Section 271(g) by its terms applies to unauthorized actions within the United States; it is irrelevant that the product was authorized to be produced outside of the United States. When the process used abroad is the same as the process covered by a United States patent, liability for infringement arises only upon importation, sale or offers, or use in the United States as set forth in § 271(g). ADM admitted at trial that it was aware of the Genetika '765 patent and that ABP's strains were derived from the Genetika strains. The district court found that the process by which ABP made the bacteria was patented in the United States, and that the sale and importation of those bacteria into the United States incurred liability under § 271(g). ADM's argument that its actions were not "without authority" must fail.

Claim Construction -- "Chromosome DNA Fragment of a Donor Bacterium"

ADM challenges the district court's construction of the term "chromosome DNA fragment of a donor bacterium." ADM does not dispute that, under the district court's construction, the findings of infringement by the strains produced by ABP for ADM are supported. ADM argues, however, that the court erred in its claim construction.

The strains acquired by ADM from ABP were G472T23 (pYN8) and G472T23 (PKYN1108:6), both of which had been developed from the bacteria made by Genetika and provided to ABP. ADM states that ABP improved on the Genetika strain through spontaneously occurring mutations and by making a new hybrid plasmid. Also, ADM asked ABP to remove from pYN8 the portion of DNA that provided resistance to ampicillin, leaving the organism resistant to tetracycline only; the portion of the DNA that produced threonine was unchanged. In response to ADM's request ABP constructed two additional plasmids, which produced the bacterial strains G472T23 (pYNSTOP) and G472T23 (pYNTE2). The district court found that these bacteria differ only in their resistance to antibiotics.

ADM argues that the hybrid plasmid that ABP combined with a plasmid molecule is not a "chromosome DNA fragment of a donor bacterium" as used in the claim, stressing the importance of "a donor bacterium." ADM states that the DNA fragment that ABP used was itself derived from a hybrid plasmid, not from a donor bacterium. Thus ADM argues that this DNA fragment does not qualify as a fragment of "a donor bacterium," and that the resultant bacterial strains are not within the scope of correctly construed claims.

The district court examined the statements of the experts for both sides on the meaning of "DNA fragment of a donor bacterium" to those skilled in this field of science. The court referred to the usage by ADM of this term, referring to ADM's submission to the Japanese Ministry of Agriculture, Forestry and Fisheries wherein ADM described the threonine operon as " *E. Coli* chromosome fragments," and the usage of this term by ABP in its Owners Manual for the ADM strains. The court described the construction of the strain G472T23 (pYN8) as follows:

ABP constructed the strain G472T23 (pYN8) from G472T23 (pYN7), which it received from Genetika. ABP used the plasmid pYN7, which had an incomplete (i.e., defective) tetracycline resistant gene, from strain G472T23 in constructing the plasmid pYN8. According to expert testimony and the "owner's manual," ABP isolated the plasmid pYN7 and cut it using restriction endonucleases so as to isolate the chromosomal DNA fragment containing the threonine operon.

Ajinomoto, 1998 WL 151411 at *23. The court concluded that "the chromosome DNA fragment can be identified in the hybrid plasmid and, therefore,

should be categorized as such."

There was extensive expert testimony on all of the issues and arguments raised by ADM. We discern no error in the district court's finding that the fact that a DNA fragment was subsequently inserted into a plasmid does not change its origin in a donor bacterium. The district court's claim construction and related conclusions are supported by the testimony of the experts and fully accord with ADM's and ABP's own usages, and are affirmed. Applying the district court's claim construction, the imported hybrid plasmid contains the chromosome DNA fragment of a donor bacterium, and is in infringement of claims 1 and 2. The finding of infringement is affirmed.

***1341** Damages

The trial ended on November 13, 1996. The district court entered its judgment and damages award on March 13, 1998, assessing a royalty of $1.23/kg of threonine sold by ADM after May 1993. ADM does not dispute the royalty rate of $1.23/kg, but disputes its assessment to most of the production after November 1996. ADM stating that the day after testimony closed it switched to a different bacterial "culture 4," and had returned to the previous "culture 3" for only a brief period in 1997. On March 27, 1998 ADM moved to amend the judgment on the ground that there was "no evidentiary basis" for the court's award of damages for most of the production after the trial ended.

Responding to the motion to amend, the district court observed that although ADM now stated that it discontinued use of the infringing strain G472T23 (pYNTE2) on the last day of testimony and switched to a different strain the following day, ADM did not inform the court that it had done so, or that it intended to do so, until after judgment was rendered. The court observed that Steven Stoddard, ADM's group leader of amino acid fermentation, testified as the final witness that the G472T23 (pYNTE2) strain was being "used today" in ADM's commercial production of threonine, and gave no hint that a change was planned for the next day. The court commented on the "fine distinctions" in that testimony, and observed that only ADM "was privy" to the correct information and that ADM "chose not to correct the record it created at trial" until after judgment. The district court denied the motion.

ADM states that it was entitled to a hearing on whether its changed bacteria were infringing. Ajinomoto responds by pointing out that ADM had denied discovery of such changes, had dissembled and avoided including culture 4 in the trial, and that the district court acted within its discretion, on these facts, in declining to accept this tardy assertion of non-infringement for production before judgment. Ajinomoto also disputes ADM's assertion that culture 4 is non-infringing.

We review a court's denial of a motion to amend the judgment for abuse of discretion. *United States v. Anthony Dell'Aquilla*, 150 F.3d 329, 338 n.8 (3d Cir. 1998) ("Our standard of review for the district court's denial of the appellants' motion to alter or amend a judgment under Fed. R. Civ. P. 59(e) is for an abuse of discretion because the underlying order was an assessment of monetary penalties."); *Donivan v. Dallastown Borough*, 835 F.2d 486, 487 (3d Cir. 1987) ("When a district court rejects a motion to alter or amend a judgment, our standard of review is whether the district court abused its discretion.") Review is plenary, however, if the district court based its decision on an error of law. *Bushman v. Halm*, 798 F.2d 651, 656 n.9 (3d Cir. 1986) ("In general, the appropriate standard of review for a motion to reconsider is whether there has been an abuse of discretion. However, to the extent the decision to deny a Rule 59 motion is based upon the interpretation and application of a legal precept, our review is plenary.")

The Supreme Court has explained Rule 59(e) as follows:

Rule 59(e) was added to the Federal Rules of Civil Procedure in 1946. Its draftsmen had a clear and narrow aim. According to the accompanying Advisory Committee Report, the Rule was adopted to "mak[e] clear that the district court possesses the power" to rectify its own mistakes in the period immediately following the entry of judgment.

White v. New Hampshire Dept. of Employment Security 455 U.S. 445 (1982).

Rule 59(e) is not a vehicle for reopening judgments to present information that was long possessed by the movant and that was directly relevant to the litigation. The Third Circuit, whose law governs this district court in procedural matters not within the Federal Circuit's exclusive jurisdiction, has instructed that:

A proper motion to alter or amend judgment "must rely on one of three major grounds: '(1) an intervening change in controlling law; (2) the availability of new evidence [not available previously]; [or] (3) the need to correct clear error [of law] or prevent manifest

injustice.' "

North River Ins. Co. v. CIGNA Reins. Co., 52 F.3d 1194, 1218 (3d Cir. 1995) (quoting *Natural Resources Defense Council v. United States Envtl. Protection Agency*, 705 F. Supp. 698, 702 (D.D.C. 1989)).

[6] Applying these grounds, there was clearly no intervening change of law. As to the second ground, the evidence that ADM had changed to an assertedly non-infringing culture ***1342** for producing threonine was neither new nor unavailable to ADM before entry of judgment. Indeed, only ADM had this information. *See, e.g., Buell v. Security General Life Ins. Co.*, 987 F.2d 1467, 1472 (10th Cir. 1993) ("When supplementing a Rule 59(e) motion with additional evidence, the movant must show either that the evidence is newly discovered [and] if the evidence was available at the time of the decision being challenged, that counsel made a diligent yet unsuccessful effort to discover the evidence.")

It was ADM's decision not to provide information about this change in its defense of non-infringement until after judgment was rendered, and indeed to provide explicit testimony that it was using the infringing strain. ADM offered no explanation of its silence, and simply argued that there was no evidence that ADM was using the ABP strains to produce threonine "at the present time," apparently referring to the time of the motion to amend. However, the evidence before the court at the time the judgment was rendered fully supported the court's assessment of damages. ADM, in its pre-trial admissions, acknowledged it was using the ABP strains and identified the specific strain used. And in a joint pre-trial statement of stipulated facts, ADM stated that it had not used any strains other than those it obtained from ABP. ADM offered no correction of these admissions before the court's judgment. *See* Fed. R. Civ. P. 36(b) ("Any matter admitted under this rule is conclusively established unless the court on motion permits withdrawal or amendment of the admission.")

ADM had requested, and been granted, a protective order prohibiting Ajinomoto from taking discovery about ADM's current research on the production of threonine. In its opposition to the protective order, Ajinomoto stated its belief that the bacterial strains ADM was developing would also infringe the '765 patent, and stated that "[p]reventing Ajinomoto from gaining access to ADM's 'new' strains now will only create the possible necessity for another law suit in the future -- a waste of both judicial resources and the resources of the parties." Ajinomoto argues that by avoiding discovery, the misleading testimony of ADM's final witness, and the complete silence as to this new defense of non-infringement based on different bacteria, ADM waived or lost any right to relief from judgment and to relitigation of the question of infringement (as ADM requested in its motion to amend).

ADM, of course, had the right to change its process to one it considered non- infringing. Had it informed the court of this defense during the lengthy pendency of the action, or had the other events to which the district court referred not occurred, the district court might have exercised its discretion differently. However, the district court has broad discretion in deciding whether to re-open a case, after the entry of judgment, to permit another infringement trial of issues that could have been resolved concurrently, with the benefit of the expertise and effort of the first trial. Abuse of discretion, on the facts hereof, has not been shown.

The Assessment of Damages

The district court assessed royalties for the period up to the filing of ADM's motion on March 27, 1998. We conclude that the district court erred in including, in the measure of damages, product produced during the period between entry of final judgment and the filing of the motion to amend. Although we do not disturb the district court's assessment of damages for the period before entry of judgment, for the period after entry of judgment ADM is entitled to raise the defense of non-infringement. The district court recognized this principle, in declining to assess damages for sales after March 27, 1998, the date ADM raised the issue of non-infringement based on process changes. Although the record and the purposes of Rule 59(e) support the district court's discretion in declining to relitigate pre-judgment infringement, ADM's post-judgment motion reasonably placed at issue ADM's infringement after judgment. Thus liability for infringement after the date of judgment requires further proceedings, during which ADM may raise the defense of non-infringement for that period.

The court's damages award is modified to the extent that production after March 13, 1988 shall not be included in the royalty obligation herein assessed.

Enhancement of Damages -- the Cross Appeal

Ajinomoto cross appeals the district court's ruling that ADM's infringement was not willful. Ajinomoto points to ADM's knowledge of ***1343** the '765 patent at the

time it bought the infringing strains from ABP for use in the United States. ADM's knowledge of Ajinomoto's exclusive rights under the United States patent, the explicit exclusion of United States rights in the Biotechnics license from Genetika, and ADM's assertion that it obtained no opinion of counsel before embarking upon its infringing activities. Ajinomoto argues that the district court clearly erred in failing to find that this was an exceptional case and in declining to enhance damages.

The district court concluded that the record as a whole did not support a finding of willfulness. The court referred to the representations made to ADM by ABP and Genetika's subsequent failure to enforce the condition in the Biotechnics license, and declined to impute bad faith to ADM's dealings with ABP. The district court observed that ADM mounted a substantial, albeit unsuccessful, challenge on the issues of validity and infringement. We do not discern clear error in the district court's finding on the issue of willful infringement.

No costs.

AFFIRMED; DAMAGES MODIFIED

FN1. *Ajinomoto Co. v. Archer Daniels Midland Co.*, 95-218-SLR (D. Del. Oct. 21, 1996 (denying summary judgment); Oct. 25, 1996 (claim construction); 1998 WL 151411, Mar. 13, 1998 (order and judgment); Oct. 7, 1998 (injunction; amended judgment); Dec. 28, 1998 (final judgment)).

FN2. Mutation genetics involves mutating strains to produce random changes in the genetic material and then screening for the desired characteristics. Recombinant DNA technology involves specific alterations to the DNA, generally by removing or inserting fragments of DNA.

FN3. A "plasmid" is a DNA molecule that can act as a carrier of specified DNA inside a cell, and that replicates independently of the chromosome DNA of the cell.

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Briefs and Other Related Documents (Back to top)

. 1999 WL 33636249 (Appellate Brief) Reply Brief for Plaintiff-Cross Appellant Ajinomoto Company, Inc. (Jun. 07, 1999)

. 1999 WL 33636251 (Appellate Brief) Combined Reply Brief for Appellant Archer-Daniels-Midland Company in Support of Its Appeal and in Opposition to the Cross-Appeal (May. 24, 1999)

. 1999 WL 33636252 (Appellate Brief) Brief for Plaintiff-Cross Appellant Ajinomoto Co. Inc. (Mar. 30, 1999)

. 1999 WL 33636248 (Appellate Brief) Brief for Appellant Archer-Daniels-Midland Company (Feb. 01, 1999)

END OF DOCUMENT

Appendix 3:

MPEP §2164.08.

112, first paragraph and a rejection under 35 U.S.C. 101) where the subject matter of a claim has been shown to be nonuseful or inoperative.

The 35 U.S.C. 112, first paragraph, rejection should indicate that because the invention as claimed does not have utility, a person skilled in the art would not be able to use the invention as claimed, and as such, the claim is defective under 35 U.S.C. 112, first paragraph. A 35 U.S.C. 112, first paragraph, rejection should not be imposed or maintained unless an appropriate basis exists for imposing a rejection under 35 U.S.C. 101. In other words, Office personnel should not impose a 35 U.S.C. 112, first paragraph, rejection grounded on a "lack of utility" basis unless a 35 U.S.C. 101 rejection is proper. In particular, the factual showing needed to impose a rejection under 35 U.S.C. 101 must be provided if a 35 U.S.C. 112, first paragraph, rejection is to be imposed on "lack of utility" grounds. See MPEP § 2107 - § 2107.03 for a more detailed discussion of the utility requirements of 35 U.S.C. 101 and 112, first paragraph.

B. Burden on the Examiner

When the examiner concludes that an application is describing an invention that is nonuseful, inoperative, or contradicts known scientific principles, the burden is on the examiner to provide a reasonable basis to support this conclusion. Rejections based on 35 U.S.C. 112, first paragraph and 35 U.S.C. 101 should be made.

Examiner Has Initial Burden To Show That One of Ordinary Skill in the Art Would Reasonably Doubt the Asserted Utility

The examiner has the initial burden of challenging an asserted utility. Only after the examiner has provided evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince one of ordinary skill in the art of the invention's asserted utility. *In re Swartz*, 232 F.3d 862, 863, 56 USPQ2d 1703, 1704 (Fed. Cir. 2000); *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (citing *In re Bundy*, 642 F.2d 430, 433, 209 USPQ 48, 51 (CCPA 1981)).

C. Rebuttal by Applicant

If a rejection under 35 U.S.C. 101 has been properly imposed, along with a corresponding rejection under 35 U.S.C. 112, first paragraph, the burden shifts to the applicant to rebut the *prima facie* showing. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). There is no predetermined amount or character of evidence that must be provided by an applicant to support an asserted utility. Rather, the character and amount of evidence needed to support an asserted utility will vary depending on what is claimed (*Ex parte Ferguson*, 117 USPQ 229, 231 (Bd. App. 1957)), and whether the asserted utility appears to contravene established scientific principles and beliefs. *In re Gazave*, 379 F.2d 973, 978, 154 USPQ 92, 96 (CCPA 1967); *In re Chilowsky*, 229 F.2d 457, 462, 108 USPQ 321, 325 (CCPA 1956). Furthermore, the applicant does not have to provide evidence sufficient to establish that an asserted utility is true "beyond a reasonable doubt." *In re Irons*, 340 F.2d 974, 978, 144 USPQ 351, 354 (CCPA 1965). Instead, evidence will be sufficient if, considered as a whole, it leads a person of ordinary skill in the art to conclude that the asserted utility is more likely than not true. See MPEP § 2107.02 for a more detailed discussion of consideration of a reply to a *prima facie* rejection for lack of utility and evaluation of evidence related to utility.

II. WHEN UTILITY REQUIREMENT IS SATISFIED

In some instances, the use will be provided, but the skilled artisan will not know how to effect that use. In such a case, no rejection will be made under 35 U.S.C. 101, but a rejection will be made under 35 U.S.C. 112, first paragraph. As pointed out in *Mowry v. Whitney*, 81 U.S. (14 Wall.) 620 (1871), an invention may in fact have great utility, i.e., may be "a highly useful invention," but the specification may still fail to "enable any person skilled in the art or science" to use the invention. 81 U.S. (14 Wall.) at 644.

2164.08 Enablement Commensurate in Scope With the Claims [R-1]

All questions of enablement are evaluated against the claimed subject matter. The focus of the examination inquiry is whether everything within the scope of

the claim is enabled. Accordingly, the first analytical step requires that the examiner determine exactly what subject matter is encompassed by the claims. The examiner should determine what each claim recites and what the subject matter is when the claim is considered as a whole, not when its parts are analyzed individually. No claim should be overlooked. With respect to dependent claims, 35 U.S.C. 112, fourth paragraph, should be followed. This paragraph states that "a claim in a dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers" and requires the dependent claim to further limit the subject matter claimed.

The Federal Circuit has repeatedly held that "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation'." *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Nevertheless, not everything necessary to practice the invention need be disclosed. In fact, what is well-known is best omitted. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further the scope of enablement must only bear a "reasonable correlation" to the scope of the claims. See, e.g., *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

As concerns the breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. *In re Moore*, 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971). >See also *Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1339, 65 USPQ2d 1452, 1455 (Fed. Cir. 2003) (alleged "pioneer status" of invention irrelevant to enablement determination).<

The determination of the propriety of a rejection based upon the scope of a claim relative to the scope of the enablement involves two stages of inquiry. The first is to determine how broad the claim is with respect to the disclosure. The entire claim must be considered. The second inquiry is to determine if one skilled in the art is enabled to make and use the entire scope of the claimed invention without undue experimentation.

How a teaching is set forth, by specific example or broad terminology, is not important. *In re Marzocchi*, 439 F.2d 220, 223-24 169 USPQ 367, 370 (CCPA 1971). A rejection of a claim under 35 U.S.C. 112 as broader than the enabling disclosure is a first paragraph enablement rejection and not a second paragraph definiteness rejection. Claims are not rejected as broader than the enabling disclosure under 35 U.S.C. 112 for noninclusion of limitations dealing with factors which must be presumed to be within the level of ordinary skill in the art; the claims need not recite such factors where one of ordinary skill in the art to whom the specification and claims are directed would consider them obvious. *In re Skrivan*, 427 F.2d 801, 806, 166 USPQ 85, 88 (CCPA 1970). One does not look to the claims but to the specification to find out how to practice the claimed invention. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1558, 220 USPQ 303, 316-17 (Fed. Cir. 1983); *In re Johnson*, 558 F.2d 1008, 1017, 194 USPQ 187, 195 (CCPA 1977). In *In re Goffe*, 542 F.2d 564, 567, 191 USPQ 429, 431 (CCPA 1976), the court stated:

> [T]o provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for "preferred" materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts.

When analyzing the enabled scope of a claim, the teachings of the specification must not be ignored because claims are to be given their broadest reasonable interpretation that is consistent with the specification. "That claims are interpreted in light of the specification does not mean that everything in the specification must be read into the claims." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 957, 220 USPQ 592, 597 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835 (1984).

The record must be clear so that the public will have notice as to the patentee's scope of protection when the patent issues. If a reasonable interpretation of the claim is broader than the description in the specification, it is necessary for the examiner to make sure the full scope of the claim is enabled. Limitations

and examples in the specification do not generally limit what is covered by the claims.

The breadth of the claims was a factor considered in *Amgen v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991). In the *Amgen* case, the patent claims were directed to a purified DNA sequence encoding polypeptides which are analogs of erythropoietin (EPO). The Court stated that:

> Amgen has not enabled preparation of DNA sequences sufficient to support its all-encompassing claims. . . . [D]espite extensive statements in the specification concerning all the analogs of the EPO gene that can be made, there is little enabling disclosure of particular analogs and how to make them. Details for preparing only a few EPO analog genes are disclosed. . . . This disclosure might well justify a generic claim encompassing these and similar analogs, but it represents inadequate support for Amgen's desire to claim all EPO gene analogs. There may be many other genetic sequences that code for EPO-type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them.

927 F.2d at 1213-14, 18 USPQ2d at 1027. However, when claims are directed to any purified and isolated DNA sequence encoding a specifically named protein where the protein has a specifically identified sequence, a rejection of the claims as broader than the enabling disclosure is generally not appropriate because one skilled in the art could readily determine any one of the claimed embodiments.

See also *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (The evidence did not show that a skilled artisan would have been able to carry out the steps required to practice the full scope of claims which encompass "any and all live, non-pathogenic vaccines, and processes for making such vaccines, which elicit immunoprotective activity in any animal toward any RNA virus." (original emphasis)); *In re Goodman*, 11 F.3d 1046, 1052, 29 USPQ2d 2010, 2015 (Fed. Cir. 1993) (The specification did not enable the broad scope of the claims for producing mammalian peptides in plant cells because the specification contained only an example of producing gamma-interferon in a dicot species, and there was evidence that extensive experimentation would have been required for encoding mammalian peptide into a monocot plant at the time of filing); *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (Where applicant claimed a composition suitable for the treatment of arthritis having a potency of "at least" a particular value, the court held that the claim was not commensurate in scope with the enabling disclosure because the disclosure was not enabling for compositions having a slightly higher potency. Simply because applicant was the first to achieve a composition beyond a particular threshold potency did not justify or support a claim that would dominate every composition that exceeded that threshold value.); *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991) (Given the relatively incomplete understanding in the biotechnological field involved, and the lack of a reasonable correlation between the narrow disclosure in the specification and the broad scope of protection sought in the claims, a rejection under 35 U.S.C. 112, first paragraph for lack of enablement was appropriate.).

If a rejection is made based on the view that the enablement is not commensurate in scope with the claim, the examiner should identify the subject matter that is considered to be enabled.

2164.08(a) Single Means Claim

A single means claim, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph. *In re Hyatt*, 708 F.2d 712, 714-715, 218 USPQ 195, 197 (Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.). When claims depend on a recited property, a fact situation comparable to *Hyatt* is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor.

2164.08(b) Inoperative Subject Matter

The presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art. *Atlas Powder Co. v. E.I.*